REMARKS

I. Status of the Application

This is a response to the Final Office Action mailed on July 28, 2009. By way of this response, Claims 18, 19 and 60-70 are now pending. Claims 18 and 19 were previously withdrawn and Claims 1–17 and 20-59 were previously cancelled. Claims 60-70 are rejected. Claim 60 has been amended and claims 63 and 65 have been cancelled, without prejudice or disclaimer to the subject matter therein. Support for the amendments can be found throughout the specification and claims as originally filed. No new matter is presented by way of the amendments.

II. Rejections Under 35 U.S.C. § 103(a)

The Examiner has rejected claims 60-70 as allegedly being unpatentable over U.S. Patent No. 6,489,346 ("the '346 patent") in view of Hatlebakk et al. (Alimentary Pharmacology and Therapeutics, 2000, Vol. 14, pages 1267-1272). Claims 60-70 are also rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent No. 2003/0191159 A1, in view of Hatlebakk *et al.*

In the Office Action, the Examiner states that "Phillips does not disclose *per se* the administration of the proton pump inhibitor compositions within about 60 minutes prior to a meal, as required by the instant claims." Office Action at p. 8. Instead, the Examiner relies on Hatlebakk *et al.* for this limitation in the pending claims. In this regard, the Examiner states that "Hatlebakk *et al.* teach the administration of the proton pump inhibitors, omeprazole and lansopazole, 15 minutes prior to a meal, to provide better acid suppression." *Id.* Applicants respectfully assert that the Examiner incorrectly arrives at the conclusion that it would have been obvious to one of ordinary skill in the art to combine these two references.

Hatlebakk *et al.* suggest that a meal is necessary for activating the parietal cells thereby allowing optimal gastric acid secretion. For example, as the Examiner has pointed out:

> Hatlebakk *et al.* suggest "omeprazole and lansoprazole inhibit gastric acid secretion by selectively and non-competitively inactivating the H^+, K^+ ATPase molecules of the parietal cell, but possible only those that are actively secreting acid. This might imply that stimulation of acid secretion by a meal is necessary for optimal inhibition of gastric secretion." Office Action at p. 11 (emphasis added).

One of ordinary skill in the art upon reading this reference would be led to conclude that compositions comprising proton pump inhibitors require an administration of close proximity in time with a meal, *e.g.*, 15 minutes or less according to Hatlebakk *et al.* for the activation of parietal cells by the meal.

Moreover, Hatlebakk *et al.* teaches away from the administration of proton pump inhibitors at greater than 15 minutes prior to a meal and also teaches that the administration of the proton pump inhibitors is to be administered near or close prior to a mealtime for maximum efficacy. For example, Hatlebakk *et al.* describes a study where subjects take omeprazole or lansoprazole in the morning 15 minutes prior to breakfast or without food until lunchtime. The results in of this study show better control of gastric acidity when the medication is taken 15 minutes before breakfast than without food until lunch. *See* Hatlebakk *et al.*, Summary, p. 1267, also *see* Table 1, p. 1269. Hatlebakk *et al.* shows that administering a proton pump inhibitor in the morning and hours before a meal (lunch) results in marginal efficacy than administering 15 minutes before a meal (breakfast). With these results, Hatlebakk *et al.* suggests to one of ordinary skill in the art that administering a proton pump inhibitor greater than 15 minutes prior to mealtime would result in decreased efficacy of acid secretion.

Further, the compositions comprising "non-enteric coated" proton pump inhibitors as presently claimed and in Phillips are significantly different than the enteric coated omeprazole in the 20 mg capsule from Astra-Zeneca and the enteric coated lansoprazole in the 30 mg capsule from TAP Pharmaceuticals used in Hatlebakk *et al.* Compositions comprising "non-enteric coated" proton pump inhibitors as presently claimed contain at least one buffering agent. Surprisingly, these buffering agents allow the present compositions to activate the parietal cells without the need for food thereby obtaining optimal gastric acid secretion, unlike the compositions described in Hatlebakk *et al.* that require food to activate the parietal cells. This allows the compositions described in the instant application to be administered at least 30 minutes or greater prior to meal. The result could in no way have been predicted by one of ordinary skill in the art given the references cited by the Examiner.

Accordingly, for at least the reasons described herein, Applicant assert that one of skill in the art would not have been motivated to combine the references relied on by the Examiner and respectfully request withdrawal of this rejection.

CONCLUSION

For at least the foregoing reasons, Applicants submit that the presently pending claims are in condition for allowance and request early and favorable consideration. Further, none of Applicants' amendments or cancellations are to be construed as dedicating any such subject matter to the public, and Applicants reserve all rights to pursue any such subject matter in this or a related patent application.

Kindly contact the undersigned attorney at (858) 350-2319 with any questions or to otherwise expedite prosecution.

Respectfully submitted,
WILSON SONSINI GOODRICH & ROSATI

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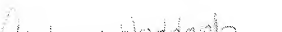

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